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10/551,820	02/10/2006	Jae-Hong Kim	012679-114	3987

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EXAMINER	
MCCORMICK, MELENIE LEE	
ART UNIT	**PAPER NUMBER**
1655	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,820	KIM, JAE-HONG	
	Examiner	Art Unit	
	Melenie McCormick	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *2,4-6 and 9-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7-8, and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I (claims 1-4 and 7-8) in the reply filed on 25 June 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants also elected the species bronchial asthma and the compound of formula 1.

Claims 16-17 have been added. Claims 2, 4- 6 and 9-16 are withdrawn from consideration. Claims 1, 3, 7-8 and 17 are presented for examination on the merits.

Requirement for Information

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

Interrogatories of Facts Known to Applicant

In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

Please provide, if known, the amount of pelargonidin which is present in a black rice which was extracted by methods instantly disclosed.

Submission of Only Pertinent Pages Where Document is Large

In responding to those requirements that require copies of documents, where the

document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

Waiver of Fee and Statement Requirements for Certain Information Disclosures

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of the requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97 where appropriate.

Contents of Good Faith Reply

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

Conclusion of Requirement That Accompanies Office Action

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Claim Objections

Claim 3 is objected to because of the following informalities: The period for this claim should end after the formula. In addition, the brackets around the term 'Formula 1' should be removed. It is suggested that Applicants amend at line 3 and replace the phrase 'to an individual in need thereof' with the phrase 'to an individual in need thereof, wherein Formula 1 is represented by the following '. Appropriate correction is required.

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 7-8 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating allergic disease, in particular those disclosed in claim 7, does not reasonably provide enablement for a method of preventing all allergic diseases, including bronchial asthma. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, use the invention commensurate in scope with these claims, as broadly claimed by Applicant.

The claims are directed to for a method for preventing or treating allergic diseases, comprising administering an effective amount of black rice extract or pelargonidin to an individual in need thereof.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re* Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation added to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

While Applicant has reasonably demonstrated a method enabling for treating allergic disease, particularly those recited in claim 7, Applicant has not demonstrated a

method for preventing any or all allergic diseases, as instantly claimed. For example, on pages 19-21 of the present specification, Examples, Applicant has demonstrated or disclosed that mice with induced asthma which were treated with black rice extract show decreased inflammation of the lungs when compared to untreated mice with induced asthma. Thus, Applicants have shown that the instantly claimed method is useful for decreasing some symptoms, or treating, asthma.

Nowhere in the specification as originally filed does Applicant demonstrate the claim-designated effect of preventing all allergic diseases comprising administering an effective amount of black rice extract or pelargonidin to an individual in need thereof. Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a method comprising the administration of black rice extract for prevention of all allergic diseases, including bronchial asthma.

It should be noted that at the time of filing of the present application, the art of medicine did not recognize the administration of black rice extract for the prevention of any and all allergic diseases, including, for example, bronchial asthma. For instance, Jindal (2007) teaches that asthma can be managed (treated), but does not teach that bronchial asthma can be prevented (see e.g. entire document). In fact, Jindal teaches that the prevention of the side effects of asthma is a goal (see e.g. page 604).

Thus, while Applicant has demonstrated a method for treating allergic disease, including, bronchial asthma, Applicant has not demonstrated the claim-designated method comprising the administration of a black rice extract or pelargonidin for the prevention of any or all allergic diseases. Therefore, it would require undue

experimentation without a reasonable expectation of success in order to determine the amounts of black rice extract or pelargonidin and the administration methods necessary to provide the claim-designated method of preventing all allergic diseases, as broadly claimed by Applicant.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the method of claim 7, wherein the allergic disease is bronchial asthma or chronic obstructive pulmonary disease" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim because claim 2 is only drawn to a method wherein the allergic disease is bronchial asthma.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (1999).

Kim et al. teach that black rice has been used in Korea for management of various allergic diseases (see e.g. page 31- Introduction). Kim et al. further teach that an extract of black rice was administered to rats which had been induced with an anaphylactic (allergic) response. Kim et al. further teach that administration of the extract reduced mortality in the anaphylactic rats (see e.g. page 33- Results). Kim et al. further teach that administration of the black rice extract also reduced histamine release in allergy- induced rats (see e.g. page 33 –Effect of OSHT on serum histamine release). Because the black rice extract is a methanol extract (see e.g. page 32 –Preparation of OSHT) and Applicant's extract is an ethanol extract, it would be expected that the extract disclosed by Kim et al. would also contain pelargonidon therein. Kim et al. further teach that the extract was administered in an amount of .0001-1.0mg/g, which, absence evidence to the contrary, would be an effective amount.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nair et al. (WO 01/15553 A1).

Nair et al. teach a method of treating an inflammatory response in an animal by administering to the animal a composition (fruit extract) which has anti-inflammatory activity (see e.g. claim 19). Nair et al. further teach that the inflammatory response may be an allergic rash (see e.g. claim 20). Nair et al. also teach that the composition comprises pelargonidin (see e.g. claim 21). Because Nair et al. disclose that the anti-inflammatory activity of the extract is mediated by pelargonidin (see e.g. page 3, lines 1-14), the pelargonidin present in the extract composition (even if only a small amount), is present in an effective amount. Even if the pelargonidin were not supplied in an 'effective' amount, based on the disclosure of Nair et al. that pelargonidin has anti-

inflammatory activity (which is useful for treating an allergic disease), one of ordinary skill in the art would reasonably expect that adjusting the amount of pelargonidin administered to an individual in need of treatment of an allergic disease would result in an effective treatment for an allergic disease, such as a rash. Therefore one of ordinary skill in the art would be motivated to provide pelargonidin in an amount effective to treat an allergic disease.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7-8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (1999) and Assem (1973).

Kim et al. beneficially teach that black rice has been used in Korea for management of various allergic diseases (see e.g. page 31- Introduction). Kim et al. further teach that an extract of black rice was administered to rats which had been induced with an anaphylactic response. Kim et al. further teach that administration of the extract reduced mortality in the anaphylactic rats (see e.g. page 33- Results). Kim et al. further teach that administration of the black rice extract also reduced histamine release in allergy- induced rats (see e.g. page 33 –Effect of OSHT on serum histamine

release). Because the black rice extract is a methanol extract (see e.g. page 32 – Preparation of OSHT) and Applicant's extract is an ethanol extract, it would be expected that the extract disclosed by Kim et al. would also contain pelargonidon therein. Kim et al. do not explicitly teach a method of treating bronchial asthma by administering an effective amount of a black rice extract to an individual in need thereof.

Assem beneficially teaches that bronchial asthma may be treated by administering antihistamines or inhibitors of anaphylactic mechanisms (see e.g. page 1191).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a black rice extract (which would necessarily contain pelargonidon therein) to an individual in need of treatment of bronchial asthma. One of ordinary skill in the art at the time the claimed invention was made would have been motivated and would have had a reasonable expectation of success in doing so based upon the beneficial teaching of Kim et al. that a black rice extract was effective in reducing an anaphylactic response and in reducing histamine release. Because Assem teaches that bronchial asthma can be treated using antihistamines or inhibitors of anaphylaxis, one of ordinary skill would reasonably expect that administration of the black rice extract with the anaphylaxis and histamine reducing effects taught by Kim et al. would treat bronchial asthma.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Patricia Leith/
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